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Subject: RE: Revised TRV Methodology

Date: 06/10/2008 05:13 PM

Thanks for all your hard work on the memo, and for the extra time to comment on the approach. I think everyone would agree that the SSD approach is a good one in that it incorporates data from several studies to theoretically provide a TRV with more confidence. However, as we know the details and how they affect the end result can not all be anticipated at this time, esp. where there is limited representative data. Therefore, I would recommend some interim review steps to ensure the data selected for use as well as the calculations are meeting objections. Flexibility in the approach where confidence is the calculation is low is appreciated. Here are my comments:

I think it is important to retain the 5th percentile information for all species, not just T&E species. Since you are calculating these values anyway, consider presenting both the 5th and 10th percentiles and their anyway, Consider presenting both the Sth and form percentiles and their associated confidence intervals in order to represent the range for the risk assessment. This will allow for a review of both values and a double check that the SSD calculation is statistically rigorous and appropriate for TRV development. The 10 percentile may be more appropriate Where you have an appropriate number of studies available on sublethal effects, as was the case in the Meador 2002 paper. This will not be the case for all chemicals and species. We should still consider applying a factor of 10 to the LOER SSDs - this factor may be supported by the 5th - 10th range when calculated.

There needs to be an estimate of confidence around the value calculated. I would recommend setting the SSD at the lower 95% prediction limit, or setting confidence criteria that if aren't met the SSD is not calculated setting confidence criteria that if aren't met the SSD is not calculated and instead we default to the lowest value approach. For cases where there is not enough data to calculate a SSD TRY, or where confidence in the value is not sufficient, I would select the most relevant LOER or NOER from a single study, as was originally agreed.

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I would emphasize that data going into the SSD should be of good quality and directly relevant to the objectives and assessment endpoints. I would exclude plants or other studies of questionable quality. Including them might increase the number of data points for the calculation, but the end result is then a TRV of questionable quality. It is also odd to include transfer to egg TRVs, but not injection and gavage studies. The route of exposure may be irrelevant as long as the residue in the body was measured at the time the effect was recorded. The proposal is to calculate a SSD where there is 5 or more points. It should be determined on a case by case basis if these five points adequately represent the populations and communities outlined in the assessment endpoints. If this is not the case, consider defaulting to the process outlined for when there are <5 data points. Also, the review process should encompass a double check that the 10th percentile SSD TRVs make sense relative the literature for organisms to be evaluated at the population level, not just for T & E species (better yet just present both as outlined above).

Ensure the SSD adequately protect populations called out separately in the assessment endpoints. This included clams and crayfish (population level) and juvenile Chinook and lamprey (individual level). If the calculated SSD is above protective clam values, for instance, the TRV should be reconsidered.

We should be developing PAH tissue residue TVs for specific species. We have clam, lumbriculus and crayfish tissue residue data for Portland Harbor, and where applicable tissue residue TRVs exist in the literature for those species they should be selected for use. These should be no confounding factors with metabolism using this approach. If there is not enough data for a SSD for one species, then lowest value approach should be used. Accumulation in invertebrates is an important line of evidence for the benthic risk assessment, where lines are evidence are

Consider using contaminant specific acute-chronic ratios instead of one mean to represent the range of all (8.3).

-Jennifer